

PATENT
Docket No. 01895284Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. ^{currently}~~(twice)~~ amended) A stable, aerosolizable composition [that is pharmaceutically suitable for rapid bronchial delivery to a lung of a subject], the composition [comprising] consisting essentially of a therapeutically effective amount of delta-9-tetrahydrocannabinol in a pharmaceutically-acceptable semiaqueous solvent comprising volumetric ratios of about 10-70 parts of ethanol, about 10-30 parts of water and ~~greater than~~ about [20] 30-80 parts of propylene glycol having a combined total of 100, provided that:

(i) upon aerosolization the composition has a mean mass median aerodynamic diameter in the range from about 1 up to about 10 μ M; [and]

(ii) the ratio of the ethanol, water and propylene glycol produces a stable clear solution near the solubility point of the delta-9-tetrahydrocannabinol such that upon administration to the lung, the partitioning of the delta-9-tetrahydrocannabinol from the solvent is enhanced so as to reach the bloodstream; and

(iii) the composition is pharmaceutically suitable for rapid bronchial delivery to the lung of a subject.

2. (original) A composition as defined in claim 1 wherein the amount of delta-9-tetrahydrocannabinol comprises from about 0.1 to about 200 mg delta-9-tetrahydrocannabinol/mL of the solvent.

3. (previously amended) A composition as defined in claim 2 wherein the amount of delta-9-tetrahydrocannabinol comprises from about 0.1 to 25 mg delta-9-tetrahydrocannabinol/mL of the solvent.

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4. (previously amended) A composition as defined in claim 2 wherein the amount of delta-9- tetrahydrocannabinol comprises about 50 mg delta-9-tetrahydrocannabinol/mL of the solvent.

5-6 (previously cancelled)

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~~5~~ ⁵ currently
(~~twice~~ amended) A composition as defined in claim 1 wherein the volumetric ratios of ethanol : water : propylene glycol are selected from those in the range of from about 10 -- 70 : about 10 : ~~greater than~~ [20] about 30 -- 80, respectively, having a combined total of 100.

~~8~~ ⁵ (previously amended) A composition as defined in claim ~~7~~ ⁵ wherein the volumetric ratios of ethanol : water : propylene glycol are about 35 : about 10 : about 55, respectively, having a combined total of 100.

~~16~~ ¹⁶ (original) A sterile and/or preserved sealed unit- or multi-unit dosage form of delta-9-tetrahydrocannabinol comprising a container and a stable composition for rapid delivery by inhalation to the lungs and subsequently to the bloodstream, as defined in Claim 1.

~~10~~ ¹⁹ (previously amended) A sterile and/or preserved sealed unit- or multi-unit dosage form as defined in Claim ~~9~~ ¹⁸ wherein said container comprises Type I Amber Glass.

~~11~~ ¹⁷ (original) The composition of claim 1, wherein the mean mass median aerodynamic diameter is from about 1 μ M to about 3 μ M.

~~12~~ ⁸ (previously amended) The composition of claim 1, wherein the ethanol is replaced with isopropanol.

13 (previously cancelled)

~~14~~ ⁹ (original) The composition of claim 1, wherein the amount of delta-9-tetrahydrocannabinol is from about 0.05% to about 15%, by weight, of the composition.

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~~15~~ (original) The composition of claim ⁹~~14~~, wherein the amount of delta-9-tetrahydrocannabinol is from about 0.02% to about 5%, by weight, of the composition.

¹¹
~~16~~ (original) The composition of claim ¹⁰~~15~~, wherein the amount of delta-9-tetrahydrocannabinol is from about 0.1% to about 4%, by weight, of the composition.

¹²
~~17~~ (original) The composition of claim 1, wherein the amount of delta-9-tetrahydrocannabinol is from about 0.01 mg to about 100 mg per kilogram of body weight of the subject.

¹³
~~18~~ (original) The composition of claim ¹²~~17~~, wherein the amount of delta-9-tetrahydrocannabinol is from about 0.025 mg to about 35 mg per kilogram of body weight of the subject.

¹⁴
~~19~~ (original) The composition of claim ¹³~~18~~, wherein the amount of delta-9-tetrahydrocannabinol is from about 0.05 mg to about 5 mg per kilogram of body weight of the subject.

¹⁵
~~20~~ (original) The composition of claim 1, further ^{consisting essentially of} comprising an agent selected from the group consisting of an ~~anti-oxidant, surfactant, buffer,~~ pH adjusting agent, bacteriostatic agent, ~~stabilizer,~~ sodium chloride, and preservative.

¹⁶
~~21~~ (original) The composition of claim 1, wherein the composition is administered to the subject one to five times a day.

¹⁷
~~22~~ (original) The composition of claim 1, wherein the subject is a human.

²⁰
~~23~~ (currently amended) A stable, aerosolizable composition [that is pharmaceutically suitable for rapid bronchial delivery to a lung of a subject], the composition [comprising] consisting essentially of a therapeutically effective amount of delta-9-tetrahydrocannabinol in a pharmaceutically-acceptable semiaqueous solvent comprising

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volumetric ratios of about 10-70 parts of ethanol, about 10-30 parts of water and ~~greater than~~
about [20] 30-80 parts of a glycol selected from the group consisting of polypropylene glycol
and polyethylene glycol having a combined total of 100, provided that:

- (i) upon aerosolization the composition has a mean mass median aerodynamic diameter in the range from about 1 up to about 10 μ M; [and]
 - (ii) the ratio of the ethanol, water and propylene glycol produces a stable clear solution near the solubility point of the delta-9-tetrahydrocannabinol such that upon administration to the lung, the partitioning of the delta-9-tetrahydrocannabinol from the solvent is enhanced so as to reach the bloodstream; and
 - (iii) the composition is pharmaceutically suitable for rapid bronchial delivery to a lung of a subject.
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